K032562

FEB - 6 2004

1.5 510(k) Summary of Safety and Effectiveness

Submitted by:	Elizabeth J. Mason, Sr. Regulatory Affairs Specialist
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Date of Submission:	August 19, 2003
Classification Name:	Porcelain Tooth (21 CFR 872.3920)
Trade or Proprietary or Model Name:	Procera® Copings and Pontic
Legally Marketed Device(s):	CeraOne Abutment System (K910611) Aluminum Oxide Powder (K001418) Y-TZP Powder and Procera® AllZirkon (K010630)

Device Description:
Nobel Biocare's Procera® Copings and Pontic are prefabricated devices intended for use as core structures of prosthetic devices, such as three-unit bridges. The Copings are also intended for use as the core structure of single crowns.

Nobel Biocare's Procera® Copings are used with the Pontic in a three-unit bridge. The Coping serves as the core structure of the two side crowns, while the Pontic serves as the core structure of the center unit in the three-unit bridge.

Nobel Biocare's Procera® Copings are also the core structure of a single crown that can be placed on both a natural or artificial tooth abutment.

Nobel Biocare's Procera® Copings and Pontic are manufactured from either Aluminum Oxide powder or Zirconium Oxide powder. The ceramic materials (both Aluminum Oxide and Zirconium Oxide) enhance the esthetics of the restoration by giving the teeth a natural appearance.

Indications for Use:
Nobel Biocare's Procera® Copings and Pontic are indicated for use as core structures of an artificial prosthesis, i.e. a three-unit bridge, for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function.

The Pontic is indicated as the core structure of the center unit and the Copings are indicated as the core structures of the two side crowns, thereby forming the three-unit bridge.

The Copings are also indicated for use as single crowns that will be cemented to a natural or artificial tooth abutment in the treatment of partially edentulous patients in order to restore chewing function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nobel Biocare AB
C/O Ms. Elizabeth J. Mason
Senior Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway,
Yorba Linda, California 92887

Re: K032562
Trade/Device Name: Procera Copings and Pontic
Regulation Number: 872.3920
Regulation Name: Porcelain Tooth
Regulatory Class: II
Product Code: ELL
Dated: November 14, 2003
Received: November 17, 2003

Dear Ms. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032562

Device Name: Procera Copings and Pontic

Indications For Use:

Nobel Biocare's Procera Copings and Pontic are indicated for use as core structures of an artificial prosthesis, i.e. a three-unit bridge, for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function.

The Pontic is indicated as the core structure of the center unit and the Copings are indicated as the core structures of the two side crowns, thereby forming the three-unit bridge.

The Copings are also indicated for use as single crowns that will be cemented to a natural or artificial tooth abutment in the treatment of partially edentulous patients in order to restore chewing function.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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